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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/568,275

05/04/2006

Shabtay Dikstein

27241U

3275

20529 7590 12/28/2009  
THE NATH LAW GROUP  
112 South West Street  
Alexandria, VA 22314

EXAMINER

BASQUILL, SEAN M

ART UNIT

PAPER NUMBER

1612

MAIL DATE

DELIVERY MODE

12/28/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/568,275	<b>Applicant(s)</b> DIKSTEIN, SHABTAY	
	<b>Examiner</b> Sean Basquill	<b>Art Unit</b> 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 18 September 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 22-31 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 22-31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)                        | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 18 September 2009 has been entered.

### ***Status of the Claims***

2. Claim 27 has been amended and new Claims 28-31 have been added. Claims 22-31 are presented for examination.

### ***Previous Rejections***

3. Applicants' arguments, filed 18 September 2009 have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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4. Claims 22-25 and 27-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,900,242 (hereinafter "Breton"), in view of U.S. Patent Application Publication 2006/0193789 (hereinafter "Tamarkin").

Breton describes the treatment of signs of skin aging, including wrinkles, fine lines, slackening of cutaneous and subcutaneous tissue, lack of skin tone, and reduced skin tone, among others. (C.1, L.46-52). Breton proposes the use of a topical skin composition comprising S-DHEA (C.2, L.1-14) and, in certain embodiments, additional hormones other than S-DHEA, including androgens such as testosterone or testosterone propionate. (C.3, L.44-49).

Concentrations of S-DHEA recited preferably fall within the range of 0.001-0.5%, but may be included in concentrations as high as 5%. (C.2, L.25-28). While no concentration range is provided for the optional additional hormone, one example uses estrone and estradiol in a total concentration of 0.01% of the composition (C.4, Example 3), which would suggest to the skilled artisan that the "other hormone" optionally included could fall within the same concentration range as those recited for S-DHEA, or at the very least, in a concentration of about 0.01%.

Breton indicates that the topical composition can be any of the forms commonly employed in topical delivery of active agents, including oily solutions, emulsions, or suspensions, for example. (C.2, L.29-41). A variety of oils are recited as useful in the formulations of such compositions. (C.3, L.3-9). Furthermore, the compositions for use in the treatment of signs of skin aging may include any additives and adjuvants conventional in the cosmetic or pharmaceutical arts, including preservatives, antioxidants, and fragrances, among others. (C.2, L.57-64).

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While indicating that generally androgens, including testosterone and its esters may serve as the additional hormone in the composition for treating signs of skin aging such as wrinkles, Breton does not specifically indicate that testosterone phenylpropionate may serve as the additional androgen.

Tamarkin indicates that a variety of hormones may be incorporated into topical compositions for the transdermal delivery of active agents, including testosterone phenylpropionate. (Para. 92 & 93). These compositions comprise, among others, organic oils as carriers. (Para. 28-40).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time of the instant invention to have used testosterone phenylpropionate in a topical composition including an androgenic steroid for the treatment of signs of skin aging such as wrinkles in women. One having ordinary skill in the art would have been motivated to do so because of Breton's teaching that androgens such as testosterone may be employed with advantage in such therapies, and Tamarkin's teaching that testosterone phenylpropionate is suitable for incorporation into oily compositions for topical application. While neither Breton nor Tamarkin specifically recite the use of an androgen in a concentration of the disclosed ranges of other hormones overlap such a concentration. In the alternative, given the general disclosure of androgen utility in the treatment of signs of skin aging, the examiner asserts the concentration of such androgens as testosterone phenylpropionate in topical compositions for the treatment of signs of skin aging is a result-effective variable, subject to optimization through the routine experimentation of the artisan possessing ordinary skill. Furthermore, while not directed to the

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treatment of signs of skin aging in women specifically, the treatment of women using such topical compositions may immediately be envisaged, and is therefore obvious.

5. Claims 22-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Breton as modified by Tamarkin as applied to claims 22-25 and 27-31 above, and further in view of U.S. Patent 6,004,566 ("Friedman").

Breton as modified by Tamarkin provides for the treatment of signs of skin aging by the topical application of an oily composition comprising testosterone phenylpropionate and other materials common to the topical cosmetic and pharmaceutical arts, but does not indicate that medium chain triglycerides may serve as the oil vehicle.

Friedman indicates that medium chain triglyceride oils (C.2, L.33-42) are commonly used as a vehicle for the topical delivery (C.2, L.15-31) of steroid compositions in amounts ranging between 0.05-2.5%. (C.2, L.59-63).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time of the instant invention to have used a medium chain triglyceride as an oil component in a topical testosterone phenylpropionate composition used in the treatment of signs of skin aging. One having ordinary skill in the art would have been motivated to do so because the art recognizes the suitability of such medium chain triglyceride oils for the topical delivery of active agents such as steroids. Generally, it is *prima facie* obvious to select a known material for incorporation into a composition, based on its recognized suitability for its intended use. MPEP 2144.07.

### ***Response to Applicants' Arguments***

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6. Applicants arguments have been fully considered and are deemed unpersuasive, in part because they relate primarily to art no longer relied upon by the examiner.

### ***Conclusion***

No Claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean Basquill whose telephone number is (571) 270-5862. The examiner can normally be reached on Monday through Thursday, between 8AM and 6PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Sean Basquill  
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/JEFFREY S. LUNDGREN/

Primary Examiner, Art Unit 1639